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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/557,519	04/25/2000	Torleif Ove Bjornson	ACBL.028.01US	8273
33603	7590	06/17/2004		EXAMINER
ACLARA BIOSCIENCES, INC.			STASIAK, JOHN S	
1288 PEAR AVENUE			ART UNIT	PAPER NUMBER
MOUNTAIN VIEW, CA 94043			1753	

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/557,519	Applicant(s) BJORNSON ET AL.
	Examiner John S. Starsiak Jr.	Art Unit 1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.

- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.

- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.

- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office after the three month period from the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 11 March 2004.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-6 and 9-17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-6 and 9-17 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsman's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____.

DETAILED ACTION***Double Patenting***

Claims 1-3, 9, 10, 13, and 14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2, 4, and 10 of U.S. Patent No. 6,103,199 in view of Manz et al. or Kamahori. Although the conflicting claims are not identical, they are not patentably distinct from each other because the following. The only differences between claim 1 of present application and claim 2 of U.S. Patent No. 6,103,199 is that claim 1 of the present application omits that the "first plate" and "second plate" are integral and claim 1 of the present application recites "a microfluidic network including a main flowpath and at least one secondary flowpath". Any other differences are merely different language to describe the same structure: 1) "a microfluidic device" (09/557,519) corresponds to "an apparatus for conducting a microfluidic process" (6,103,199), 2) "a second plate comprising an array of microfluidic units wherein each unit comprises a microfluidic network of a plurality of reservoirs connected by interconnected channels of capillary dimensions..." (09/557,519) corresponds to "a second plate...comprising a planar array of microfluidic networks of cavity structures and channels..." (6,103,199); 3) "each unit having one reservoir for fluid communication with one sample receiving element of the first plate" corresponds to "each of said microfluidic networks is adapted for fluid communication with a corresponding sample receiving element of said first plate" (6,103,199). Regarding the structure of the microfluidic device recited in claim 1 of the present application, microfluidic devices with "a main flowpath and at least one secondary flowpath" are

notoriously well known in the microfluidics art. Manz et al. and Kamahori are examples of a multitude of references which disclose this teaching. Hence, it the would have been obvious to one of ordinary skill in the art at the time of the invention that the "microfluidic networks" of 6,103,199 could comprise "a main flowpath and at least one secondary flowpath" because microfluidic networks with this structure are notorious well-known in the art. Regarding the omission of the first and second plates being integral in claim 1, it would be obvious to one of ordinary skill in the art that the claimed invention of 6,103,199 would function if the plates were fasten to each other instead of being integral. Regarding claims 2, 3, and 10 of the present application, "wherein the number of said mcrofluidic units is a multiple of 8" (claim 2), "wherein said array of sample receiving elements has the format of a 96 well micro titer well format" (claim 3), "wherein said array of microfluidic units is comprised of rows of 8 units" (claim 10) are equivalent to "wherein said array of sample wells conforms to the spacing format of a 96, 192, 384 or 1536 well plate"(claim 4 of 6,103,199) because in order to meet the limitation of claim 4, the number of microfluidic networks must inherently be multiples/rows of 8 and the array of sample receiving elements must inherently have the spacing format of a 96 well microtiter plate. Regarding claim 9 of the present application, "wherein said first plate is integral with the second plate" is equivalent to "a second plate integral with said first plate" (claim 2 of 6,103,199). Regarding claim 13 of the present application, the structural recitation in the preamble of the claim (a method claim) equivalent to the structural recitations recited in the process steps a, b, and c of claim 10 (6,103,199). The three process steps ("contacting", "transferring", and "operating") of the present

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application are equivalent to step a, b, and c, respectively, of claim 10 (6,103,199).

Regarding claim 14 of the present application, “wherein said first plate is integral with the second plate” is equivalent to “a second plate integral with said first plate” of claim 10 (6,103,199).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 and 9-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Bjornson et al.

The applied reference has a common inventor with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

This new rejection is being made because of applicant’s amendments of the claims. Specifically, the original claims were so broad that they had support in U.S.

Patent Application No. 09/153,214, filed 15 September 1998 and U.S. Provisional

Patent Application No. 60/059,332, filed 19 September 1997. However, the applicant's amendment of the claims is so extensive that the claims no longer have any support in the above applications.

Claims 1 and 9 read on either claims 1 or claim 2 except for " a microfluidic network... including a main flowpath and at least one secondary flowpath". This particular reads on Bjornnson et al. [column 19, lines 59-62]: "The microfluidic network has interconnected cavity structures and channels, the latter forming one or more flowpaths resulting in an interconnected system. In general, there is a main flowpath and one or more secondary flowpath". Regarding claims 2 and 10, Bjornson et al. teaches [column 22, lines 35-40]: "It is to be understood that the microfluidic network plates may have any number of separate networks including more than or less than 96. The number of microfluidic networks may be multiples of 96 where the number is greater than 96 or multiples of 8 where the number is less than 96.". The limitation recited in claim 3 is inherent in Bjornson et al., i.e. if the devices of Bjornson et al. have 96 networks they must have 96 sample receiving elements. Regarding the "film" recited in claim 4, Bjornson et al teaches [column 24, line 23-29 and column 25, lines 62 &63]: "The integrated apparatus of the present invention may have any conventional configuration capable of comprising the first and second plates and their respective component parts. The cavities and channels of the second plate are usually present on the surface of a planar substrate where the substrate will usually, though not necessarily be covered with a cover plate to seal the microfluidic networks present on

the surface of the planar substrate from the environment.”. “The cover may be a more or less rigid, or it may be a film...”. Regarding “the number of microfluidic units is a multiple of 8” recited in claim 4, see the rejection of claim 2 above. Regarding claim 5, Bjornson et al. [column, lines 66 & 67]: “...glass for the first plate and plastic for the second plate.”. Regarding claim 6, Bjornson et al. [column 23, lines 30-37]: “With regard to electrodes, some or all of the electrodes may be within the second plate with external connections to power supplies that may be part of an instrument into which the present apparatus is inserted. On the other hand, some or all of the electrodes might be on a separate part (e.g. built into an instrument into which the present invention is inserted), such that the electrodes can be immersed into the appropriate fluid reservoirs at the time of use.”. Regarding claim 11, see the rejection of claims 1 and 9 above. Regarding claim 12, Bjornson et al teaches [column 25, lines 1-5]: “For applications where it is desired to have a disposable integrated device, due to ease of manufacture and cost of materials, the device typically is fabricated from a plastic. For ease of detection and fabrication, the entire apparatus may be made from a plastic material...”. The structural recitations recited the preamble of claim 13 read on the structural recitations recited in steps a, b, and c of claim 10 of Bjornson et al. The “transferring” step and the “operating” step of claim 13 read on steps b and c of claim 10 of Bjornson et al. The “contacting” step of claim 13 inherent reads on step a of claim 10 of Bjornson because in order to perform the transferring process recite in step a of claim 10 one must inherently contact the array of sample receiving elements with the array of sample wells. The structural limitation recited in claim 14 is recited in step b of claim 10 of

Bjornson et al. Claim 15 reads on Bjornson et al. [column 18, lines 14-17]: "When the elements 102 are in the sample, an aliquot of sample is transferred to the element. For capillaries, transfer is conveniently by capillary action.". Regarding claim 16, Bjornson et al. teaches [column 1, lines 6-10]: "This invention relates generally to the receiving and dispensing of samples such as in the field of separation of biomolecules and, in particular, separations by capillary electrophoresis and the use of capillary electrophoresis to detect such biomolecules.". Regarding claim 17, Bjornson et al. teaches [column 8, lines 19 to 23]: "The array of processed samples is simultaneously transferred for capillary electrophoresis to an array of capillary electrophoresis columns. Capillary electrophoresis is simultaneously conducted on the array of the capillary electrophoresis columns...".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 6, 9, 13, 14, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chow et al. in view of Parce et al.

Chow et al. discloses all the particulars recited in claim 1 except that Chow et al. has a single microfluidic unit and the claim recites an array of microfluidic units. Regarding the two plate construction of the device recited in claim 1, Chow et al.

teaches [column 6, line 65 to column 7, line 19]: "The channels and/or chambers of the microfluidic devices are typically fabricated into the upper surface of the bottom substrate or portion, as microscale grooves or indentations, using the above described microfabrication techniques. The top portion or substrate also comprises a first planar surface, and a second surface opposite the first planar surface. In the microfluidic devices prepared in accordance with the methods described herein, the top portion also includes a plurality of apertures, holes, or ports disposed therethrough, e.g. from the first planar surface to the second planar surface. The first planar of the top substrate is then mated, e.g., placed in contact with, and bonded to the planar surface of the bottom substrate, covering and sealing the grooves and/or indentations in the surface of the bottom substrate, to form the channels and/or chambers (i.e., the interior portion) of the device at the interface of these two components. The holes in the top portion of the device are orientated such that they are in communication with at least one of the channels and/or chambers formed in the interior portion of the device from grooves or indentations in the bottom substrate." The "sample reservoir element" recited in claim 1 reads on capillary element 138 (illustrated in Figures 1 & 3). Figures 1B, 5A, and 5B illustrate that the capillary element 138 is located on the plate that does not contain the grooves and/or indentations. The "main flowpath" and "at least one secondary flowpath" read on "main analysis channel 104" and "channels 114 and 116" of Chow et al., respectively. Parce et al. teaches that a plurality of microfluidic units of the type described by Chow et al. can be formed on a single substrate. Specifically, Parce et al. teaches [column 30, lines 39 to 43]: "As shown (Figure 7), each chip includes a number

of discrete assay channels 706, each having a separate interface 708, e.g., pipettor, for introducing test compounds into the device. There interfaces are used to pip test compounds into the device...". It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a plurality of microfluidic units in the device of Chow et al. because this modification would increase throughput. Regarding claims 9 and 14, Chow et al. [column 7, lines 9 to 11]: "The first planar surface of the top substrate is then mated, e.g., placed into contact with, and bonded to the planar surface of the bottom substrate,...". Method claims 13 to 17 read on the inherent method of using the device(s) of Chow et al. as modified in view of Parce et al. Regarding claim 16, Chow et al teaches [column 12, lines 59 to 63]: "Once the sampled material is transported into the analysis channel of the microfluidic device, it is then subjected to the desired analysis. For example, the material may be injected into a separation channel and separated into its component parts, e.g. electrophoretically.

Claims 2, 3, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chow et al. in view of Parce et al. as applied to claim 1 above, and further in view of Sundberg et al.

Parce et al. does not recite any specific number of microfluidic units (Figure 7 illustrates 12). Hence, the number of microfluidic units in Parce et al is not critical. Sundberg et al. discloses a device for loading samples onto a microfluidic apparatus, that includes a plurality of pins 38. Sundberg et al. teaches [column 5, lines 59 to 63]: "The pins may optionally be aligned in an array corresponding to at least a portion of a standard microtiter plate, e.g. 12 rows of 8 pins on 9 mm spacings and other liquids with

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conventional chemical and biological techniques.”. Hence, the embodiment of Sundberg et al. comprising 96 pins would be used to simultaneously load samples onto a microchip with 96 devices arranged in a 12 by 8 matrix. Hence, it would have been obvious to one of ordinary skill in the art to provide the device of Chow et al. as modified in view of Parce et al. with 96 microfluidic units arranged in a 12 by 8 matrix on 9 mm spacings because this would allow the device to be interfaced with a standard microtiter plate as taught by Sunderberg et al.

Response to Arguments

Applicant's arguments with respect to claims 1-6 and 9-17 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Starsiak Jr. whose telephone number is (571) 272-1346. The examiner can normally be reached on Monday-Friday from 7:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



John S. Starsiak Jr.

09 June 2004



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